UNITED STATES DISTRICT COURT FOR
THE WESTERN DISTRICT OF WASHINGTON
AT TACOMA

ROSANN BRIDGES and ROBERT BRIDGES, and the marital community comprised thereof, Plaintiffs, v. HOWMEDICA OSTEONICS d/b/a STRYKER ORTHOPAEDICS and STRYKER CORP., Defendants.	NO. COMPLAINT FOR DAMAGES JURY DEMAND

I. INTRODUCTION

COME NOW Plaintiffs, Rosann Bridges and Robert Bridges ("Plaintiffs"), by and through the undersigned counsel, and bring this complaint against Defendants, HOWMEDICA OSTEONICS d/b/a STRYKER ORTHOPAEDICS and STRYKER CORP. (hereinafter collectively "Defendants" and "Stryker"), and allege as follows:

1. This is an action for damages relating to Defendants' development, testing, assembling, manufacture, packaging, labeling, preparing, distribution, marketing, supplying, and/or selling the defective product(s) sold under the names "LFIT Anatomic V40 Femoral Head" and "The Accolade TMZF® Hip Stem" (hereinafter, "Defective Devices").

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II. PARTIES

2. Plaintiffs ROSANN BRIDGES and ROBERT BRIDGES are citizens and residents of Tacoma, Pierce County, Washington.

3. Defendant, Howmedica Osteonics Corporation, (hereinafter "HOWMEDICA"), d/b/a STRYKER ORTHOPAEDICS is a corporation organized and existing under the laws of New Jersey having its principal place of business located at 325 Corporate Drive, Mahwah, NJ 07430. Defendant does business throughout the United States, including in the State of Washington. Defendant Howmedica Osteonics d/b/a Stryker Orthopaedics is a wholly owned subsidiary of parent corporation, Stryker Corporation.

4. Defendant Stryker Corporation is the parent corporation organized and existing under the laws of the State of Michigan, with its principal place of business in Kalamazoo, Michigan. Defendant does business throughout the world and throughout the United States, including the State of Washington. Stryker holds itself out as "one of the world's leading medical technology companies and is dedicated to helping healthcare professionals perform their jobs more efficiently while enhancing patient care. Stryker provides innovative orthopaedic implants as well as state-of-the-art medical and surgical equipment to help people lead more active and more satisfying lives." (Source: www.stryker.com.)

5. Upon information and belief, at all times herein mentioned, the employees of Defendants, their subsidiaries, affiliates, and other related entities, as well as the employees of each of the individual Defendants' subsidiaries, affiliates, and other related entities, were the agents, servants and employees of Defendants, and at all relevant times, were acting within the purpose and scope of said agency and employment. Whenever reference in this Complaint is made to any act or transaction of Defendants, such designations shall be deemed

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to mean that the principals, officers, employees, agents and/or representatives of the Defendants committed, knew of, performed, authorized, ratified and/or directed such transactions on behalf of Defendants while actively engaged in the scope of their duties.

III. JURISDICTION AND VENUE

6. The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a) because complete diversity exists between the Plaintiffs, who are citizens of the State of Washington, which is different from the States where the Defendants are incorporated and have their principal places of business, and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

7. Venue is proper within this District pursuant to 28 U.S.C. § 1391 and it is a judicial district where Defendants are subject to personal jurisdiction in accordance with 28 U.S.C. §§ 1391(a) and (c) because Defendants did (and do) business within the State of Washington and have had continuous and systematic contacts with the State of Washington, and they have consented to jurisdiction in the State of Washington.

IV. THE PRODUCTS

8. At all times material hereto, Defendants developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the defective products under the name "LFIT Anatomic V40 Femoral Head and The Accolade® TMZF Hip Stem" (hereinafter, "Defective Devices"), either directly or indirectly, to members of the general public, including Plaintiff Rosann Bridges.

9. Upon information and belief, Defendants' Defective Devices were placed into the stream of interstate commerce and were implanted in Plaintiff Rosann Bridges' right hip on July 13, 2006 and in her left hip on July 20, 2011.

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10. As a direct and proximate result of Defendants placing the Defective Products into the stream of commerce, Plaintiff Rosann Bridges has suffered and continues to suffer both injuries and damages, including but not limited to: past, present and future physical and mental pain and suffering; and past, present and future medical, hospital, rehabilitative and pharmaceutical expenses, and other related damages.

11. In or around March 2001, Stryker received clearance from the FDA to market the LFIT Anatomic V40 Femoral Head in the United States in the United States under the 510(k) process, claiming substantial similarity with other Howmedica Osteonics femoral heads.

12. On March 16, 2000, Defendants received FDA clearance to sell its Accolade TMZF prosthetic hip stem in the United States in the United States under the 510(k) process, claiming substantial similarity with other Howmedica Osteonics hip stems.

13. The Accolade TMZF Stem is a hip replacement prosthesis. It is indicated for patients requiring primary total hip arthroplasty or replacement due to joint disease. It is also indicated for use in revision procedures where other treatments or device have failed.

14. The Accolade TMZF Stem is a monoblock, single piece artificial hip replacement device that is designed to be implanted into the patient's femur. The Accolade TMZF Stem is designed to be used with any number of bearing surface components comprised of the modular ball or artificial femoral head and an acetabular cup or socket.

15. The titanium stem is manufactured utilizing a proprietary titanium alloy consisting of titanium, molybdenum, zinc and iron. Howmedica's alloy was designed and patented by Defendants and is different than the titanium alloy employed in the manufacture of prosthetic hip implants. The Defendants claim in their Accolade TMZF Stem promotional

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materials that TMZF alloy is both stronger and less rigid than other titanium alloys. They also claim that the particular titanium alloy has been tested and proven by Defendants to demonstrate improved wear resistance, reducing the potential for generation of particulate metallic wear debris.

16. Stryker's LFIT Anatomic V40 femoral head is one of the modular balls or heads designed to be used with the Accolade TMZF Stem. It is made of cobalt/ chromium alloy.

17. Defendants marketed the LFIT V40 Cobalt Chromium femoral head to be paired with the Accolade TMZF Stem to help maximize a patient's hip movement, as well as stability and dislocation resistance.

18. At all times material hereto, the LFIT Anatomic V40 femoral head and Accolade TMZF Stem implanted in the Plaintiff was designed, manufactured, marketed, retailed, distributed, and/or supplied by Defendants.

19. After a period of time following the implantation of the Defective Devices, Plaintiff Rosann Bridges began experiencing discomfort in the area of her Defective Devices.

20. A MARS MRI revealed "moderately large fluid collections… compatible with development of a micrometallic toxicity complication" Plaintiff Rosann Bridges' left hip.

21. Based upon these findings and Plaintiff's symptoms, Plaintiff Rosann Bridges underwent revision surgery on her left hip at Franciscan Health Systems in Pierce County, WA, on November 30, 2015 performed by Dr. Steven Teeny. Dr. Teeny noted that the difficulty of the revision surgery was 50% greater "due to the large amount of necrotic tissue requiring extensive debridement." During the revision surgery, Dr. Teeny encountered "a very large pocket of brownish-reddish necrotic debris with complete loss of all soft tissues from the posterior half of the greater trochanter down approximately 10 cm nearly to the insertion

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of the gluteus maximus tendon and then anteriorly as well." Dr. Teeny indicated that the tissue "looked reminiscent of a typical trunnionosis" and when the femoral head was dislocated, a "large amount of black material around the trunnion and in the femoral head" was discovered. A new ceramic femoral head was implanted in order to avoid another cobalt chromium LFIT Anatomic V40 Femoral Head from interacting with the dissimilar metal titanium alloyed stem and to prevent further corrosive action.

22. Upon information and belief, Plaintiff Rosann Bridges underwent revision surgery on her right hip at Franciscan Health System in Pierce County, WA, on November 30, 2015 performed by Dr. Steven Teeny.

THE LFIT V40 COCR FEMORAL HEAD & STRYKER ACCOLADE FEMORAL STEM HISTORY

23. In or around March 2001, Stryker received clearance from the FDA to market the LFIT Anatomic V40 Femoral Head. The basis of Stryker's application was that the predicate devices were made of cobalt chromium alloy femoral heads conforming to ASTM F1537 and cobalt chromium alloy of these femoral heads are fabricated from cobalt chromium alloy conforming to ASTM F799.

24. LFIT stands for "Low Friction Ion Treatment" and this technology was marketed to "enhance the material properties of CoCr to reduce frictional forces against Ultra-high-molecular-weight polyethylene (UHMWPE) surfaces."

25. Stryker advertised that an LFIT treated head better simulates the joint by allowing increased lubrication between the components and "LFIT ™ heads demonstrated a 28% reduction in linear wear over CoCr heads in 100 patients at a minimum 3-year follow up."

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26. Stryker issued a Class 2 Device Recall of a large number of the Stryker LFIT Anatomic V40 chromium/cobalt heads. The Recall notice was posted on the FDA website on November 9, 2016 which states that the reason for the recall is "Stryker received several complaints describing incidence of harm secondary to taper lock failure for specific lots of numerous catalog numbers of LFIT Anatomic CoCr V40 Femoral Heads."

27. The recall cites trunnion failure, metal wear, adverse tissue reaction and the need for revision surgery as causes for recalling the femoral heads. Ms. Bridges suffered each of the above and the combination resulted in the need for revision surgery due to failure of her LFIT Anatomic V40 head in conjunction with the Accolade TMZF Stem.

28. In or around March 2000, Stryker released its Accolade TMZF Hip Stem, the latest evolution in the Company's Meridian Titanium Femoral Stem, the Howmedica Asymmetric Stem Femoral Component, the Osteonics Omnifit AD-HA Hip Stem Series all cleared for market between the years of 1994 and 1997.

29. According to Stryker's materials, the Accolade TMZF Stem was developed to maximize a patient's hip range of motion, increase stability, and prevent dislocation. These materials also state that the Accolade TMZF Hip Stem is designed to be used with V40 Femoral Heads, which are offered in both forged Vitallium alloy (CoCrMo) and zirconia ceramic. The Accolade TMZF Stem is also designed with two neck angles, the standard 132 degrees and extended 127 degrees offset, to assist with joint stability and proper restoration of joint kinematics without lengthening the leg. The neck lengths are proportional relative to the patient's body geometry to accommodate a wider patient population using a standard femoral head.

30. Defendants claim in their promotional materials that the TMZF alloy "provides

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the opportunity to reduce the neck geometry thus optimizing the available range of motion while maintaining strength." Additionally, Stryker states the "unique composition of titanium, molybdenum, zirconium, and iron, it achieves a superior combination of flexibility, strength, and notch resistance when compared to other alloys used in orthopaedic implants."

31. The Accolade TMZF Stem combines the material characteristics of TMZF (Ti-12Mo-6Zr-2Fe) with a Circumferential Plasma Titanium plasma spray coating and PureFix HA. The LFIT Anatomic V40 Femoral Head was commonly used with the Accolade TMZF Hip Stem, which is made from chromium/cobalt alloy. Defendants claim that laboratory testing demonstrates the compatibility of these materials without concern for fretting and corrosion.

32. Despite Defendants' claims, this material combination has been reported to cause corrosion. For decades, scientists have reported the occurrence of accelerated fretting and corrosion issues when dissimilar metals are combined. In their marketing and sale of the device, Defendants represented and warranted that proprietary materials alleviate concerns for this problem.

33. Furthermore, in 2012, Stryker recalled its Rejuvenate and ABG II modular hip systems. These two systems employed the same TMZF titanium metal in the femoral stem. The modular neck of both recalled devices were manufactured from chromium/cobalt. These devices were recalled after reports surfaced indicating excessive device failure due to fretting and corrosion at the taper junction where these dissimilar metals were joined.

34. Patients in whom Stryker Rejuvenate and ABG II hip stems had been implanted were experiencing device failure, symptoms and diagnostic findings similar to Plaintiff, Rosann Bridges. Information disseminated by Stryker at or about the time of the recall cited

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this failure mechanism as the reason for the recall.

35. Since the recall, revision rates for the Rejuvenate and ABG II have been reported to exceed 50% in a very short period of time.

36. Upon information and belief, Stryker redesigned its Accolade Stem and abandoned the use of TMZF titanium. Instead, its new Accolade II Stem to be manufactured from a different titanium alloy and is compatible with V40 heads.

V. CAUSES OF ACTION

COUNT I:

COMMON LAW NEGLIGENCE

37. Plaintiffs reallege and incorporate by reference the allegations set forth above.

38. Defendants designed, manufactured, marketed, detailed, and advertised both the LFIT V40 Cobalt Chromium femoral head and Accolade TMZF Stem and to physicians and consumers.

39. As a result, Defendants had a duty to perform each of these functions reasonably and with reasonable and due care for the safety and well-being of patients in whom the devices would be implanted.

40. Defendants failed to use reasonable and due care for the safety and well-being of those in whom the devices would be implanted and is therefore negligent in the following respects:

a. Defendants failed to adequately warn of the increased risks of fretting, corrosion and heavy metal toxicity associated with the use of the LFIT V40 Cobalt Chromium femoral head and Accolade TMZF Stem.

b. Defendants failed to adequately design and manufacture the devices to

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insure that when combined each would not fret, corrode, erode, deteriorate and induce severe metal toxicity in patients. The flaws include but are not limited to:

i. The incompatibility of LFIT V40 chromium/cobalt heads with the TMZF titanium;

ii. Use of the TMZF alloy that contains a modulus of elasticity with far inferior stiffness characteristics to other available titanium alloys;

iii. Use of the TMZF alloy with a known corrosion/fretting profile inferior to other titanium alloys;

iv. Poor design of the taper junction between femoral head and neck such that micro motion was predictable;

v. Poor design of the Accolade neck such that the “softer” TMZF alloy would induce suffer from excessive bending and movement;

vi. Poor manufacturing practices such that the taper junction between the femoral head and neck do not “fit” as deigned and intended;

vii. Not restricting authorized or recommended use of the Accolade TMZF Stem to ceramic heads only;

viii. Allowing and promoting the use of large metal heads on Stryker’s small and insufficient V40 trunnion which would predictably lead to excessive motion, fretting, mechanically

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assisted crevice corrosion and ultimately device failure; and

ix. A combination of the above factors leads to rapid, severe heavy metal cast off causing soft tissue and bony necrosis, pain and premature failure of the device.

c. Defendants failed to adequately test the "Defective Devices" and their combination to insure they would not fret, corrode, erode, deteriorate and induce severe metal toxicity in the patient;

d. Prior to marketing the "Defective Devices," Defendants failed to conduct anything other than simple, basic bench testing. At the time Defendants designed the "Defective Devices," sufficient scientific art and knowledge existed to conduct testing that would have exposed the defects in the LFIT V40 chromium/cobalt head when implanted in patients with an Accolade TMZF Stem;

e. In fact, Stryker has likely conducted testing that reveals the incompatibility of these two materials when used in this design;

f. Defendants made affirmative representations that the "Defective Devices" would not fret or corrode in the human body. These representations were false and misleading to both physicians and the consumer;

g. Defendants trained its sales force to detail the "Defective Devices" utilizing representations the Defendants knew or should have known to be false, creating in the minds of both surgeons and consumers the belief that the "Defective Devices" were safe for its intended use;

h. Defendants specifically marketed the "Defective Devices" as a safe

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alternative to metal-on-metal bearing surface "Defective Devices" that had been widely publicized as capable of causing premature failure due to heavy metal toxicity;

i. Defendants failed to manufacture the products to Defendants' own internal specifications such that the taper junction between the neck and stem prematurely failed causing metal debris cast-off and severe metal toxicity in patients;

j. Defendants failed to adequately test the LFIT V40 chromium/cobalt components compatibility with components made of TMZF alloy in an effort to prevent corrosion and fretting at the bearing surface junction of this stem;

k. Defendants failed to promptly act upon reports of failure or warn surgeons such that the LFIT V40 Cobalt Chromium femoral head femoral head continued to be implanted in combination with the Accolade TMZF Stem well after it should have been recalled or redesigned; and

l. Defendants chose these materials to be used in combination as a system at a time when safer alternative designs and materials were available.

41. The above conduct exhibits Defendants' failure to exercise reasonable care. It was foreseeable that such negligence would lead to premature device failure as well as severe, debilitating injury that is permanent.

42. As a direct and proximate result of the Defendants' negligence, Plaintiff suffered severe physical pain and suffering, emotional distress, mental anguish, loss of the capacity for the enjoyment of life, medical and nursing expenses, surgical expenses, lost wages and loss of

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earning capacity. These damages have occurred in the past and will continue into the future.

WHEREFORE, Plaintiffs respectfully requests that Plaintiffs be granted relief against Defendants, as contained in the Prayer For Relief.

COUNT II

STRICT LIABILITY - FAILURE TO WARN RCW 7.72 *et seq.*

43. Plaintiffs reallege and incorporate by reference the allegations set forth above as if set forth herein.

44. The LFIT V40 Cobalt Chromium femoral head and Accolade TMZF Stem implanted into Plaintiff contained no warnings or in the alternative, inadequate warnings as to the risk that the products could independently cause significant heavy metal toxicity or cause significant heavy metal toxicity when used together.

45. The LFIT V40 Cobalt Chromium femoral head and Accolade TMZF Stem implanted into Plaintiff contained no warnings that these components posed significant increased risk of fretting, corrosion and heavy metal toxicity in patients or combination thereof posed significant increased risk of fretting, corrosion and heavy metal toxicity in patients.

46. The LFIT V40 Cobalt Chromium femoral head and Accolade TMZF Stem implanted into Plaintiff contained no warning against the use of these devices together.

47. The warnings that accompanied the LFIT V40 Cobalt Chromium femoral head and Accolade TMZF Stem failed to provide that level of information that an ordinary consumer would expect when using a LFIT V40 Cobalt Chromium femoral head with an Accolade implant in a manner reasonably foreseeable to the Defendants.

48. Had Plaintiff received a proper or adequate warning as to the risks associated

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with using the LFIT V40 Cobalt Chromium femoral head and an Accolade implant, Plaintiff would not have used the products.

49. Had Plaintiff's surgeon received a proper or adequate warning as to the risks associated with using a LFIT V40 Cobalt Chromium femoral heads in combination with a Accolade TMZF Stem, he would not have recommended the device; would have used an alternate device, or at a minimum, provided Plaintiff with adequate warning and obtained her informed consent. As stated above, had Plaintiff received an adequate warning, she would not have agreed to have the LFIT V40 Cobalt Chromium femoral head and Accolade TMZF Stem implanted in her.

50. The failure to warn of the risks of the LFIT V40 Cobalt Chromium femoral head and Accolade TMZF Stem caused serious damage to Plaintiff including bodily injury, the need for revision surgery, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, aggravation of a preexisting condition, loss of the capacity for the enjoyment of life, the costs of medical care and expenses, loss of earnings and loss of the ability to earn money, all of which damage and losses will continue in the future.

WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted relief against Defendants, as contained in the Prayer For Relief.

COUNT III

STRICT LIABILITY – DESIGN DEFECT RCW 7.72 *et seq.*

51. Plaintiffs reallege and incorporate by reference the allegations set forth above as if set forth herein.

52. This is an action based upon design defect against Defendants.

53. Integral to the design of the LFIT V40 Cobalt Chromium femoral head and

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Accolade TMZF Stem were their compatibility with one another.

54. Defendants' LFIT V40 Cobalt Chromium femoral head and Accolade TMZF Stem are designed in such a way that, when used as intended in combination, it causes serious, permanent and devastating damage to patients in whom the devices are implanted. The damage and mechanism of injury have been previously described herein.

55. When combined with an Accolade TMZF Stem, Defendants' LFIT V40 Cobalt Chromium femoral heads do not perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to Defendants.

56. When combined with LFIT V40 Cobalt Chromium femoral heads, Defendants' Accolade Stems do not perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to Defendants.

57. The risks of using Defendants' LFIT V40 Cobalt Chromium femoral heads in combination with Accolade TMZF Stems outweigh the benefits of using them.

58. The risks of using Defendants' Accolade TMZF Stems in combination with LFIT V40 Cobalt Chromium femoral heads outweigh the benefits of using them.

59. The LFIT V40 Cobalt Chromium femoral head and Accolade TMZF Stem installed in Plaintiff's hips were defectively designed and safer alternative designs exist.

60. The design defect in Defendants' LFIT V40 Cobalt Chromium femoral head and Accolade TMZF Stem caused serious damage to Plaintiff including bodily injury, the need for revision surgery, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, aggravation of a preexisting condition, loss of the capacity for the enjoyment of life, the costs of medical care and expenses, loss of earnings and loss of the ability to earn money, all of which damage and losses will continue in the future.

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WHEREFORE, Plaintiffs respectfully requests that Plaintiffs be granted relief against Defendants, as contained in the Prayer For Relief.

COUNT IV

STRICT LIABILITY- MANUFACTURING DEFECT RCW 7.72 *et seq.*

61. Plaintiffs reallege and incorporate by reference the allegations set forth above as if set forth herein.

62. This is an action based on a manufacturing defect against the Defendants.

63. The LFIT V40 Cobalt Chromium femoral heads and Accolade TMZF Stems were designed for implantation into the human body and to last long-term. They are also designed to be compatible with human tissue and bone.

64. The LFIT V40 Cobalt Chromium femoral head and Accolade TMZF Stem implanted in the Plaintiff prematurely failed as previously described.

65. The LFIT V40 Cobalt Chromium femoral head and Accolade TMZF titanium stem were manufactured in a substandard manner such that either:

a. The Cobalt Chromium femoral head was manufactured such that it did not "fit;"

b. The Cobalt Chromium femoral head was fashioned in such a manner that it did not maintain structural integrity when implanted in the biologic environment;

c. The Cobalt Chromium femoral head was fashioned in such a manner that it did not maintain structural integrity when mated with an Accolade TMZF stem;

d. The tapers were poorly manufactured so that they did not "fit;"

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e. The TMZF titanium material was fashioned in such a manner that it did not maintain structural integrity when implanted in the biologic environment;

f. The TMZF titanium material was fashioned in such a manner that it did not maintain structural integrity when mated with a Cobalt Chromium femoral head; and

g. The HA coating of the stem, the Hydroxyapetite, became loose and caused third body wear thus enhancing the metallosis process.

66. This combination was not compatible with human tissue, muscle and bone. Through a process of fretting and corrosion, it released heavy metals into the Plaintiff's body causing severe and permanent destruction of essential muscle and tissue. Defendants failed to manufacture the product in a manner that prevented fretting and corrosion and, in fact, manufactured the product such that it caused fretting and corrosion.

67. The LFIT V40 Cobalt Chromium femoral head and Accolade TMZF Stem installed in Plaintiff's hips contained a manufacturing defect.

68. The manufacturing defect in the LFIT V40 Cobalt Chromium femoral head and Accolade TMZF Stem caused serious damage to Plaintiff including bodily injury, the need for revision surgery, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, aggravation of a preexisting condition, loss of the capacity for the enjoyment of life, the costs of medical care and expenses, loss of earnings and loss of the ability to earn money, all of which damage and losses will continue in the future.

WHEREFORE, Plaintiffs respectfully requests that Plaintiffs be granted relief against

Defendants, as contained in the Prayer For Relief.

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COUNT V

BREACH OF EXPRESS WARRANTY AND IMPLIED WARRANTIES RCW 7.72 *et seq.*

69. Plaintiffs reallege and incorporate by reference the allegations set forth above as if set forth herein.

70. Through their public statements, their descriptions of the LFIT V40 Cobalt Chromium femoral head and their promises relating to these heads, Defendants expressly and impliedly warranted, among other things, that the LFIT V40 Cobalt Chromium femoral heads were efficacious and safe for its intended use and was designed and constructed of materials that would prevent fretting and corrosion and would provide superior component longevity to or over competing products.

71. Through their public statements, their descriptions of the Accolade TMZF Stem and their promises relating to the Accolade TMZF Stem, Defendants expressly and impliedly warranted, among other things, that the Accolade TMZF Stem was efficacious and safe for its intended use and was designed and constructed of materials that would prevent fretting and corrosion and would provide superior component longevity to or over competing products.

72. Product materials expressly warranted that "the TMZF alloy is specifically tailored for high performance in orthopaedic applications, optimizing the material properties that are key elements in the comfort of your patients and the long–term clinical success of the implant." Warrantors go on to state that "laboratory testing with TMZF further demonstrates improved wear resistance, reducing the potential for generation of particulate metallic wear debris" as well as "[W]ith its demonstrated advantages in material properties, TMZF alloy, combined with Howmedica Osteonics' clinically successful implant geometries and coating

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technologies, takes orthopaedic design to new standards of performance."

73. These warranties came in the form of (i) publicly made written and verbal assurances of safety; (ii) press releases and dissemination via the media of uniform promotional information that was intended to create demand for the LFIT V40 Cobalt Chromium femoral head and Accolade TMZF Stem, but which contained material misrepresentations and failed to warn of the risks of the LFIT V40 Cobalt Chromium femoral head and Accolade TMZF Stem; (iii) verbal assurances made by Defendants' consumer relations personnel to the public about the safety of the LFIT V40 Cobalt Chromium femoral head and Accolade TMZF Stem and downplaying of the risks of use associated with the LFIT V40 Cobalt Chromium femoral head and Accolade TMZF Stem and; (iv) false and misleading written information supplied by Defendants.

74. Plaintiff further alleges that all of the aforementioned written materials are known to Defendants and in their possession, and it is Plaintiff's reasonable belief that these materials shall be produced by Defendants and be made of record once Plaintiff is afforded the opportunity to conduct discovery.

75. When Defendants made these express warranties, Defendants knew the purpose for which the LFIT V40 Cobalt Chromium femoral head and Accolade TMZF Stem were to be used and warranted them to be in all respects safe and proper for such purpose, including their use in combination.

76. Defendants drafted the documents and/or made the statements upon which these warranty claims are based, and in so doing, defined the terms of those warranties.

77. The LFIT V40 Cobalt Chromium femoral heads and Accolade Stem do not conform to Defendant's representations in that these devices are not safe, and produce serious

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side effects, particularly when combined with one another.

78. Defendants knew of the use for which these devices were intended and impliedly warranted the LFIT V40 Cobalt Chromium femoral head and Accolade TMZF Stem to be of merchantable quality and fit for such use together.

79. The LFIT V40 Cobalt Chromium femoral head and Accolade TMZF Stem manufactured and supplied by Defendants were not of merchantable quality and were not fit for the ordinary and/or particular purpose for which they were intended as, among other defects, the risks included fretting and corrosion and the likelihood of painful and debilitating revision surgery.

80. Plaintiff and/or her physician reasonably relied upon the skill and judgment of Defendants as to whether the LFIT V40 Cobalt Chromium femoral head and Accolade TMZF Stem were of merchantable quality and fit/safe for their intended and particular use and purpose, and upon Defendants' implied warranty as to such matters, including use together.

81. Defendants knew or had reason to know that Plaintiff and/or her physician would reasonably rely upon the skill and judgment of Defendants as to whether the LFIT V40 Cobalt Chromium femoral head and Accolade TMZF Stem were of merchantable quality and fit/safe for their intended and particular use and purpose, and upon Defendants' implied warranty as to such matters, including use together.

82. Contrary to such warranties, the LFIT V40 Cobalt Chromium femoral head and the Accolade TMZF Stem did not conform to Defendants' promises, descriptions or affirmations of fact and were not of merchantable quality or adequately packaged, labeled, promoted or fit for the ordinary purposes for which such "Defective Devices" are used.

83. Defendants, therefore, breached their express and implied warranties to Plaintiff

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herein in violation of common and statutory law, including RCW 62A.2-313 – 62A.2-315 *et seq.* codifying the Uniform Commercial Code, by manufacturing, marketing, and selling the LFIT V40 Cobalt Chromium femoral head and Accolade TMZF Stem to Plaintiff herein and causing damages as will be established at trial

WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted relief against Defendants, as contained in the Prayer For Relief.

COUNT VI

LOSS OF CONSORTIUM

84. Plaintiffs reallege and incorporate by reference the allegations set forth above as if set forth herein.

85. Plaintiff Robert Bridges is and was at all relevant times the lawful spouse of Plaintiff Rosann Bridges and as such, was entitled to the comfort, enjoyment, society and services of his spouse.

86. As a direct and proximate result of the foregoing, Plaintiff Robert Bridges was deprived of the comfort and enjoyment of the services and society of his spouse and has suffered and will continue to suffer economic loss, and has otherwise been emotionally and economically injured. Plaintiff Robert Bridges' injuries and damages are permanent and will continue into the future. The Plaintiffs seek actual damages from the Defendants as alleged herein.

87. For the reasons set forth herein, Plaintiff Robert Bridges suffered and will continue to suffer the loss of his loved one's support, companionship, services, society, love and affection and is entitled to recover for his loss of consortium in an amount to be determined by a jury.

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WHEREFORE, Plaintiffs respectfully requests that Plaintiffs be granted relief against Defendants, as contained in the Prayer For Relief.

VI. DEMAND FOR JURY TRIAL

88. Pursuant to Federal Rule of Civil Procedure 38(b), the Plaintiffs hereby demand a jury for all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiffs pray for judgment against the Defendants as follows:

a) Awarding compensatory damages resulting from Defendants' negligence, breach of warranties and for strict liability.

b) Awarding actual damages to the Plaintiff Rosann Bridges and Robert Bridges incidental to their purchase and use of the LFIT V40 Cobalt Chromium femoral head and Accolade TMZF Stem in an amount to be determined at trial;

c) Awarding loss of consortium damages for Plaintiff Robert Bridges;

d) Awarding pre-judgment and post-judgment interest to the Plaintiffs;

e) Awarding the costs and the expenses of their litigation to the Plaintiffs;

f) Awarding reasonable attorneys' fees and costs to the Plaintiffs as provided by law; and

g) Granting all such other relief as the Court deems necessary, just and proper.

Dated this 24th day of March, 2017.

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